

REMARKS

Claims 1-34 constitute the pending claims in the present application. Claim 3-24 and 28-34 have been withdrawn from consideration as directed to a non-elected invention. Claims 1-2 and 25-27 are currently under consideration. Applicants add new claims 35-38. Support for the subject matter of these claims is found throughout the specification. No new matter has been entered. Specific support can be found, for example, on page 70, line 33 – page 71, line 9. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

1. Applicants note that the invention of Group II, claims 1-2 and 25-27, has been elected and is currently under consideration. Applicants further note that the claims have been examined with respect to the elected species represented in Exhibit 1 of the previously filed Restriction Requirement.
2. Claims 1-2 are objected to for referring to hedgehog polypeptides which allegedly constitute non-elected subject matter. Applicants' amendments to claims 1 and 2 to delete reference to "hedgehog polypeptides" are believed to obviate this objection.
3. Claims 1-2 and 25-27 are rejected under 35 U.S.C. 102(e) as allegedly anticipated by Porter et al. Applicants traverse this rejection.

As a first point, Applicants respectfully disagree with the applicability of *In re Best* and *Ex parte Gray*, as cited by the Examiner on page 4 of the last Office Action, to the patentability of the claimed subject matter. As correctly indicated by the Examiner, these cases address the question of patentability of products in view of prior disclosure of the product, and indicate that "... the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences." (page 4, prior Office Action). However, in this case, the question is not whether prior disclosure of a product anticipates claims directed to that same product, but rather, whether the prior disclosure of a use of a product anticipates claims directed to a different use of that same product. Thus, reliance on *In re Best* and *Ex parte Gray* is misplaced and does not support the instant rejection.

Moving on to the issue at hand, Porter et al. fail to satisfy the criteria necessary to anticipate the claimed invention. Specifically, Porter et al. fail to teach or suggest each and every limitation of the present claims. (See MPEP 2131). In accordance with MPEP 2131 and with the Courts, "a claim is anticipated only if each and every element as set forth in the claim is

found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the...claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

The present claims are directed to methods of promoting angiogenesis by administering an “angiogenic amount” of a hedgehog agonist. The disclosure in Porter et al. of exemplary therapeutic methods, for example in the promotion of wound healing, neither teaches nor suggests administration of an angiogenic amount of hedgehog agonist. Although the Examiner asserts that the use of a hedgehog agonist in the promotion of wound healing would necessarily result in the promotion of angiogenesis, this is not necessarily the case, and the Examiner has provided no references to support the assertion that wound healing is *necessarily* accompanied by an increase in angiogenesis.

Wound healing is a complex biological process. Wound healing involves a diverse array of processes including cell proliferation, cell differentiation, and inflammation. Thus, even if, *arguendo*, angiogenesis may accompany wound healing, this is not necessarily the case. This point is further relevant to Applicants’ discussion of anticipation based on the doctrine of inherency, as outlined in detail below.

Applicants traversal of this rejection applies equally to a rejection maintained under the doctrine of inherency. For inherent anticipation of method claims, if a claimed method comprises steps identical to those of a method practiced in the prior art, and the same result would have been achieved in the prior art method, the accidental or unwitting achievement of that result cannot constitute anticipation. *In re Marshall*, 578 F.2d 301, 198 USPQ 344 (CCPA 1978). In *Marshall*, the PTO Board used the *Physician’s Desk Reference* (PDR) as a basis for a rejection of the applicant’s weight control process. The applicant’s process involved anesthetizing certain intestinal nerve ends receptors with oxethazaine. The anesthesia inhibited the release of certain appetite stimulating hormones thereby inhibiting appetite. The PDR had disclosed that oxethazaine inhibits the release of gastrointestinal hormones, and such inhibition would be useful for treating certain gastrointestinal ailments. In reversing the Board’s rejection, the court held that the PDR did not teach the use of the compound as a weight control drug. Addressing the issue of inherency, the court further stated that “[I]f anyone ever lost weight by

following the PDR teachings it was an unrecognized accident. An accidental or unwitting duplication of an invention cannot constitute an anticipation.” (*id.* 304)

Porter et al. teach the administration of hedgehog agonists for the treatment of wound healing. As outlined above, wound healing is a complex process involving an array of cellular events. If the wound healing promoted by the methods taught in Porter et al. was accompanied by angiogenesis, it was as an unpredictable, unrecognized, and unwitting result of these methods. Since the Supreme Court’s decision in *Tilghman v. Proctor*, such an accidental attainment of a result, absent any recognition of that result, was held insufficient for anticipating an invention. *Tilghman v. Proctor*, 102 U.S. 707 (1880). Accordingly and consistent with holdings ranging from the Supreme Court’s decision in *Tilghman* to the Board’s decision in *Marshall*, Porter et al. cannot anticipate the presently claimed invention.

Even in *Marshall*, where the claimed method and the prior art method were identical, the rejection based on inherent anticipation failed to stand due to the failure of the prior art to appreciate the result. The present case goes even farther because, as outlined in detail above, the prior art fails to teach or suggest each and every limitation of the pending claims. Thus, unlike in *Marshall*, the claimed method and prior art method are **not** identical. “[T]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.” MPEP 2112

Applicants contend that Porter et al. fail to satisfy the criteria for expressly or inherently anticipating the claimed invention. Reconsideration and withdrawal of this rejection are respectfully requested.


CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**.

Date: August 31, 2004

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Respectfully Submitted,



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